HFD-613

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-516/S-002

McNeil Consumer Products Company
Attention: Vivian A. Chester
Vice President, Regulatory Affairs
7050 Camp Hill Road
Fort Washington, Pennsylvania 19034-2299

JUN -4 1998

Dear Ms. Chester:

Please refer to your supplemental new drug application dated June 20, 1997, received June 23, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Children's Motrin (ibuprofen suspension) Suspension, 100 mg/mL.

The supplemental new drug application provides for incorporation of a revised allergy warning and storage statement as specified in the Agency's letter dated March 3 1, 1997, and other additional labeling changes that you have proposed.

We have completed the review of this supplemental new application, including the submitted draft labeling, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the enclosed draft labeling. Accordingly, the supplemental new application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed draft labeling. Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FINAL PRINTED LABELING" for approved supplemental NDA 20-516/S-002. Approval of this submission by FDA is not required before the labeling is used.

Please revise-the labeling at the time of next printing or within 180 days, whichever comes first, as follows:

New or revised language is accented:

A. Read Product Information Statement (All cartons)

Read all product information before using. Keep this box for important information. This product is ~~intended~~ for ~~use in~~ children only.

B. Headings (All cartons and containers)

All headings and information presented in all capital letters (IMPORTANT, ACTIVE INGREDIENT, USES, DIRECTIONS, WARNINGS, SHAKE WELL BEFORE USING, SHAKE WELL, DOSING CHART, ASPIRIN SENSITIVE CHILDREN, CALL YOUR DOCTOR IF, DO NOT USE, and AGE, WEIGHT, AND DOSE in the dosing table) should be revised to upper and lower case.

C. Use Statement (All cartons and containers)

The current uses statement should be deleted and replaced with the following statement:

Uses: Temporarily:
- **reduces fever**
- **relieves minor aches and pains due to the common cold, flu, sore throat, headaches, and toothaches**

D. Directions (All cartons and containers)

A fifth statement should be added under "Directions" as follows:

5. If stomach upset occurs while taking this product, give with food or milk.

E. Aspirin Sensitive Statement (All cartons and containers)

The current "Aspirin Sensitive" warning should be deleted and replaced with the following statement:

Aspirin sensitive children: Although this product does not contain aspirin, **it** may cause a severe reaction in people allergic to aspirin. Do not give to children who have had any of the following reactions to any pain reliever/fever reducer:

- allergic reaction
- difficulty breathing
- shock
- asthma
- hives
- swelling

F. Call Your Doctor If Statements (All cartons and 4 and 2 fl oz containers)

- **stomach upset gets worse or lasts**

(Statement to immediately follow bullet concerning a lack of relief or worsening of symptoms .)

G. Stomach Upset Statement (All cartons and 4 and 2 fl oz containers)

The following statement should be deleted from the "Warnings section":

"If stomach upset occurs while taking this product, give with food or milk. If stomach irritation gets worse or lasts, call your doctor. "

The information contained in these statements has been modified above (refer to D. and F.).

Should additional information relating to the safety and effectiveness of the drug become available, revision of the labeling may be required.

Should a letter communicating important information about this drug product (i.e., a " Dear Doctor" letter) be issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20852-9787

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact Stephanie Mason, Project Manager, at (301) 827-2275.

Sincerely yours,

Debra L. Bowen, M.D.
Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Enclosure

OCT + 6 1998

8708010

Children's Motrin®

IBUPROFEN ORAL SUSPENSION
100 mg per 5 mL (teaspoon)
Fever Reducer/Pain Reliever

Child-Resistant Safety Cap
Unbreakable Bottle

08708010

WARNINGS

ASPIRIN SENSITIVE CHILDREN:
Although this product does not contain aspirin, it may cause a severe reaction in people allergic to aspirin. Children's Motrin may cause:

- asthma
- hives
- shock (low blood pressure)
- allergy
- shortness of breath
- swelling of the face

Children's Motrin can cause serious reactions, similar to those listed above, requiring **immediate** medical attention. These reactions can occur after taking a single dose or any subsequent dose in persons both with, and without, prior reaction to Children's Motrin or other pain reliever/fever reducer.

CALL YOUR DOCTOR IF:

- Your child is under a doctor's care for any serious condition or is taking any other drug.
- Your child has problems or serious side effects from taking fever reducers or pain relievers.
- Your child does not get any relief within first day (24 hours) of treatment, or pain or fever gets worse.
- Redness or swelling is present in the painful area.
- Sore throat is severe, lasts for more than 2 days or occurs with fever, headache, rash, nausea or vomiting.
- Any new symptoms appear.

DO NOT USE:

- With any other product that contains ibuprofen, or any other pain reliever/fever reducer, unless directed by a doctor.
- For more than **3 days** for fever or pain unless directed by a doctor.
- For stomach pain unless directed by a doctor.
- If your child is dehydrated (significant fluid loss) due to continued vomiting, diarrhea or lack of fluid intake.
- **If plastic bottle wrap imprinted with "Safety Seal®" or inner foil seal on bottle opening imprinted with "Safety Seal®" is broken.**

IMPORTANT:

- **Keep this and all drugs out of the reach of children. In case of accidental overdose, seek professional assistance or contact a poison control center immediately.**
- If stomach upset occurs while taking this product, give with food or milk. If stomach upset gets worse or lasts, call your doctor.

Children's Motrin®
IBUPROFEN ORAL SUSPENSION
100 mg per 5 mL (teaspoon)
Fever Reducer/Pain Reliever

IMPORTANT: Read all product information before using. Keep this box for important information. This product is intended for use by children only.

ACTIVE INGREDIENT: Ibuprofen.

USES: For Temporary:

- **Reduction of fever**
- **Relief of minor aches and pains** due to colds, flu, sore throat, headaches and toothaches

DIRECTIONS:

1. Find right dose on chart below. If possible, use weight to dose; otherwise use age.
2. Measure dose with cup provided.
3. Repeat dose every **6–8 hours**, if needed.
4. Do not use more than **4 times a day**.

SHAKE WELL BEFORE USING

DOSING CHART

WEIGHT (lb)	AGE (yr)	DOSE (teaspoon)
Under 24	Under 2	Consult Doctor
24–35	2–3	1 tsp
36–47	4–5	1½ tsp
48–59	6–8	2 tsp
60–71	9–10	2½ tsp
72–95	11	3 tsp

One Dose Lasts 6–8 Hours

Children's Motrin®
IBUPROFEN ORAL SUSPENSION
100 mg per 5 mL (teaspoon)
Fever Reducer
Pain Reliever

Lasts up to **8 hours**

BERRY-FLAVORED LIQUID
Alcohol Free

Children's Motrin®
IBUPROFEN ORAL SUSPENSION
100 mg per 5 mL (teaspoon)
Fever Reducer/Pain Reliever

Questions or Comments?
Call toll free 1–800–962–5357
Or ask your Pharmacist, Doctor or Health Care Professional.

See bottom of box for lot number and expiration date.
Store at room temperature: 15°–30°C (59°–86°F)

Inactive Ingredients: Citric acid, cornstarch, artificial flavors, glycerin, polysorbate 80, purified water, sodium benzoate, sucrose, xanthan gum, FD&C Red #40, D&C Yellow #10.

McNEIL

McNEIL Consumer Products Co.
Division of McNEIL-PPC, Inc.
Fort Washington, PA 19034 USA

U.S. Patent No. 5,374,659

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EXP: